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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,126	11/28/2000	Hui-Quan Han	01017/35966A	5693

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[REDACTED] EXAMINER

SLOBODYANSKY, ELIZABETH

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1652

DATE MAILED: 12/31/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/724,126	HAN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Elizabeth Slobodyansky	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.  
 2a) This action is FINAL.                  2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-66 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) \_\_\_\_ is/are rejected.  
 7) Claim(s) \_\_\_\_ is/are objected to.  
 8) Claim(s) 1-66 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.  
 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.  
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
     a) The translation of the foreign language provisional application has been received.  
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ . | 6) <input type="checkbox"/> Other: _____                                    |

Art Unit: 1652

## **DETAILED ACTION**

Claims 1-66 are pending.

### ***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8, 10, 11, 46-48 and 59-64 (in part), drawn to a DNA of SEQ ID NO: 1, a vector containing it, a cell transformed with the same, a method of use of said cell, classified in class 435, subclass 183.
- II. Claims 1-8, 10, 11, 46-48 and 59-64 (in part), drawn to a DNA of SEQ ID NO: 3, a vector containing it, a cell transformed with the same, a method of use of said cell, classified in class 435, subclass 183.
- III. Claims 9, 12-14, 16-18, 40-45, 49, 50 and 58 (in part), drawn to a polypeptide of SEQ ID NO:2 and a method of use thereof, classified in class 435, subclass 183.
- IV. Claims 9, 12-14, 16-18, 40-45, 49, 50 and 58 (in part), drawn to a polypeptide of SEQ ID NO:4 and a method of use thereof, classified in class 435, subclass 183.
- V. Claim 15, drawn to a polypeptide of SEQ ID NO:6, classified in class 435, subclass 183.

Art Unit: 1652

- VI. Claims 19-21 and 23-38 (in part), drawn to an antibody against a polypeptide of SEQ ID NO:2 and a method of use thereof, classified in class 530, subclass 387.1.
- VII. Claims 19-21 and 23-38 (in part), drawn to an antibody against a polypeptide of SEQ ID NO:4 and a method of use thereof, classified in class 530, subclass 387.1.
- VIII. Claims 20, 21 and 23 (in part), drawn to an antibody against a polypeptide of SEQ ID NO:6 and a method of use thereof, classified in class 530, subclass 387.1.
- IX. Claims 22 and 39 (in part), drawn to a hybridoma producing an antibody against a polypeptide of SEQ ID NO:2, classified in class 435, subclass 326.
- X. Claims 22 and 39 (in part), drawn to a hybridoma producing an antibody against a polypeptide of SEQ ID NO:4, classified in class 435, subclass 326.
- XI. Claims 51-54 (in part), drawn to a method of treatment of a subject with a polypeptide of SEQ ID NO:2, classified in class 424, subclass 94.1.
- XII. Claims 51-54 (in part), drawn to a method of treatment of a subject with a polypeptide of SEQ ID NO:4, classified in class 424, subclass 94.1.

Art Unit: 1652

- XIII. Claim 55, drawn to a method of diagnosing the level of huE3 $\alpha$ , classified in class 435, subclass 4.
- XIV. Claims 56 and 57 (in part), drawn to a device comprising a polypeptide of SEQ ID NO:2, classified in class 424, subclass 424.
- XV. Claims 56 and 57 (in part), drawn to a device comprising a polypeptide of SEQ ID NO:4, classified in class 424, subclass 424.
- XVI. Claim 65 (in part), drawn to a method of treatment of an animal with a DNA of SEQ ID NO:1, classified in class 514, subclass 44.
- XVII. Claim 65 (in part), drawn to a method of treatment of an animal with a DNA of SEQ ID NO:3, classified in class 514, subclass 44.
- XVIII. Claim 66, drawn to a transgenic non-human animal, classified in class 800, subclass 13.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-II, III-IV-V and VI-VII are patentably distinct because a DNA, a polypeptide and an antibody are different compounds each with its own chemical structure and function, and they have different utilities. The DNA molecules of inventions I-II are not limited in use to the production of a polypeptide of inventions III-IV and can be used as hybridization probes and a polypeptide of inventions III-IV can

Art Unit: 1652

be obtained by a materially different method such as by the biochemical purification. While a polypeptide of inventions III-IV-V is related to an antibody of inventions VI-VII-VIII as being cognate antigen, the structure of an antibody is unpredictable from the structure of the polypeptide. An antibody of inventions VI-VII-VIII can cross-react with other polypeptides.

Inventions I-VIII and IX-X are patentably distinct because inventions I-VIII are directed to a specific compound characterized by a specific chemical structure while a hybridoma cell line is a complex entity comprising a great number of different molecules.

Hybridomas of inventions IX and X are patentably distinct as comprising different molecules.

Inventions I-X are patentably distinct from inventions XIV-XV because inventions I-X are directed to a specific compound characterized by a specific chemical structure or a hybridoma cell line that do not contain synthetic parts required for a device.

Inventions I-X are patentably distinct from invention XVIII because inventions I-X are directed to specific compounds characterized by a specific structure and cells characterized by specific composition while a transgenic organism of invention XVIII is a complex live entity comprising a great number of different cells comprising different molecules acting in correlated mechanisms.

Art Unit: 1652

Inventions III-IV and XI-XII-XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown:

(1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant a polypeptide of inventions III-IV can be used for the production of an antibody of inventions VI-VII, in an *in vivo* method of treatment of inventions XI-XII and in an *in vitro* assay of invention XIII.

Inventions I-II and XVI-XVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown:

(1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case a DNA of inventions I-II can be used in a method of treatment of invention XVI-XVII and as hybridization probes.

Inventions XI-XII and XIII are patentably distinct because they are directed to materially different methods. Methods of inventions XI-XII are *in vivo* methods while a method of invention XIII is an *in vitro* method.

Art Unit: 1652

Inventions XI-XII and XVI-XVII are patentably distinct because they are directed to materially different methods employing different compounds such as a polypeptide and a DNA. These methods employ different protocols, chemicals and have different utility.

Inventions I and II, III and IV, etc. are patentably distinct because they are directed to materially different products and methods of use thereof. A protein having a specific sequence set forth in SEQ ID NO: 2, for example, is a distinct compound with its own chemical structure and function, and it has a specific utility.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

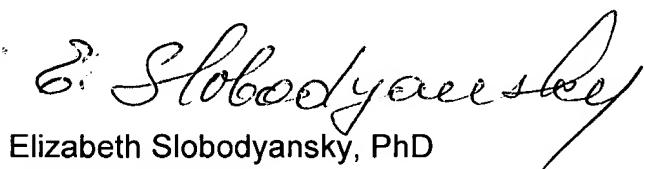
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Art Unit: 1652

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.



Elizabeth Slobodyansky, PhD  
Primary Examiner

December 26, 2001